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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,609	10/13/2000	Roberto Weinmann	BMS-0010	9813

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EXAMINER	
GALITSKY, NIKOLAI M	
ART UNIT	PAPER NUMBER
1631	7

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/687,609	Applicant(s) WEINMANN et al.	
	Examiner Nikolai M Galitsky	Art Unit 1631	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Drawings

Applicant is hereby notified that the required timing for the correction of the drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant applications or a notice of a failure to fully respond to this Office action.

Election/Restrictions.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I Claims 1 – 14, 18 and 19, drawn to a crystal of an AR LBD, classified in Class 530, subclass 358. If this group is elected, then the below specie election requirement also is required.

Group II Claims 15 - 17, drawn to a machine-readable data storage medium, classified in Class 703, subclass 1.

Group III Claim 20, drawn to a method for obtaining structural information about a molecule or a molecule complex of unknown structure, classified in Class 702, subclass 27.

Group IV Claim 21, drawn to a computational method for designing an androgen receptor synthetic ligand, classified in Class 703, subclass 11.

Group V Claims 22 - 28, drawn to a method for identifying a compound that modulates androgen receptor activity, classified in Class 703, subclass 2.

Group VI Claim 29, drawn to an AR modulator, classified in Class 552, subclass 540.

Group VII Claim 30, drawn to a method for treating prostate cancer by administering an effective amount of an AR modulator, classified in class 514, subclass 178.

Group VIII Claims 31 and 32, drawn to a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an AR modulator, classified in class 514, subclass 178.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and II are patentably distinct. The inventions of Group II is drawn a machine-readable data storage medium, whereas in contrast Group II is drawn to the crystals of an AR LBD or an AR LBD with an AR-LBD ligand. The inventions of these Groups have different functions, different effects.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a crystal of an AR LBD of Group I is used in alternative methods of Groups III and IV, drawn to a method for obtaining structural information about a molecule or a molecule complex of unknown structure and a computational method for designing an androgen receptor synthetic ligand, respectively. In addition, a crystal of an AR

LBD can be used in a method, for example, of homology modeling, which is also a clearly distinct usage of a crystal data.

The inventions of Group I and Group IV are patentably distinct. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case a crystal of an AR LBD of Group I is used in alternative inventions of Groups II and V, drawn to a machine-readable data storage medium and a method for identifying a compound that modulates androgen receptor activity, respectively. In addition, a crystal of an AR LBD of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group V are related as product and process of use. In the instant case a crystal of an AR LBD of Group I is used in alternative inventions of Groups II and IV, drawn to a machine-readable medium and a computational method for designing an androgen receptor synthetic ligand, respectively. In addition, a crystal of an AR LBD of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group VI are drawn to the distinct products. The products are distinct physically, chemically and functionally and can have different use. These Groups are also classified in different classes and subclasses.

The inventions of Group I and Group VII are related as product and process of use. In the instant case a crystal of an AR LBD of Group I is used in alternative inventions of Groups II and IV, drawn to a machine-readable medium and a computational method for designing an androgen receptor synthetic ligand, respectively. In addition, a crystal of an AR LBD of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group VIII are related as product and process of use. In the instant case a crystal of an AR LBD of Group I is used in alternative inventions of Groups II and IV, drawn to a machine-readable medium and a computational method for designing an androgen receptor synthetic ligand, respectively. In addition, a crystal of an AR LBD of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Groups II and III are patentably distinct. The invention of Group II is directed to a machine-readable data storage medium comprising a data storage material encoded with machine-readable data, which is not required, for example, for generating an x-ray diffraction data from a crystallized molecule or a molecule complex of the invention of Group III.

The inventions of Groups II and IV are patentably distinct. The invention of Group II is drawn to a machine-readable data storage medium comprising a data storage material encoded

with machine-readable data, which is not required for a computational method for designing an androgen receptor synthetic ligand.

The inventions of Groups II and V are patentably distinct. The invention of Group II is drawn to a machine-readable data storage medium comprising a data storage material encoded with machine-readable data, which is not required for a method for identifying a compound that modulates androgen receptor activity.

The inventions of Groups II and VI are patentably distinct. The invention of Group II is drawn a machine-readable data storage medium comprising a data storage material encoded with machine-readable data that is not required for the invention of Groups VI, which is directed to an AR modulator. The inventions are distinct physically, chemically and functionally and can have different use. The AR modulator can be used, for example, as a drug, which is also a clearly distinct usage of the AR modulator.

The inventions of Groups II and VII are patentably distinct. The invention of Group II is drawn to a machine-readable data storage medium comprising a data storage material encoded with machine-readable data, whereas the invention of Groups VII is directed to a method for treating prostate cancer by administering an effective amount of an AR modulator. The inventions of these Groups have at least different functions or different modes of operation.

The inventions of Groups II and VIII are patentably distinct. The invention of Group II is drawn to a machine-readable data storage medium comprising a data storage material encoded with machine-readable data, whereas the invention of Groups VIII is drawn to a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by

administering an effective amount of an AR modulator. The inventions of these Groups have different functions, different effects, and different modes of operation.

The methods of Groups III and IV are patentably distinct. The invention of Group III is drawn to a method for obtaining structural information about a molecule or a molecule complex of unknown structure, whereas the invention of Groups IV is directed to a computational method for designing an androgen receptor synthetic ligand. The inventions of these Groups have different functions, different effects, and different modes of operation.

The methods of Groups III and V are patentably distinct. The invention of Group III is drawn to a method for obtaining structural information about a molecule or a molecule complex of unknown structure. The invention of Groups V is drawn to a method for identifying a compound that modulates androgen receptor activity. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups III and VI are patentably distinct. The invention of Group III is directed to a method for obtaining structural information about a molecule or a molecule complex of unknown structure, whereas the invention of Groups VI, which is directed to an AR modulator that can be practiced as a drug, which is a distinct practice.

The methods of Groups III and VII are patentably distinct. The invention of Group III is drawn to a method for obtaining structural information about a molecule or a molecule complex of unknown structure by generating an x-ray diffraction data from a crystallized molecule or a molecule complex. The invention of Groups VII is drawn to a method for treating prostate cancer by administering an effective amount of an AR modulator. The inventions of these Groups have different functions, different effects, and different modes of operation.

The methods of Groups III and VIII are patentably distinct. The invention of Group III is drawn to a method for obtaining structural information about a molecule or a molecule complex of unknown structure by generating an x-ray diffraction data from a crystallized molecule or a molecule complex. The invention of Groups VIII is drawn to a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an AR modulator. The inventions of these Groups have different functions, different effects, and different modes of operation.

The methods of Groups IV and V are patentably distinct. The invention of Group IV is drawn to a computational method for designing an androgen receptor synthetic ligand. The invention of Groups V is drawn to a method for identifying a compound that modulates androgen receptor activity. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Group IV and Group VI are related as process of use and product. In the instant case the AR modulator of Group VI is used in alternative inventions of Groups VII and VIII, drawn to a method for treating prostate cancer and a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an AR modulator, respectively. In addition, the AR modulator of Group VI can be used in a method of molecular modeling using x-ray crystallography software, which is also a clearly distinct usage of the AR modulator.

The methods of Groups IV and VII are patentably distinct. The invention of Group IV is drawn to a computational method for designing an androgen receptor synthetic ligand. The invention of Groups VII is drawn to a method for treating prostate cancer by administering an

effective amount of an AR modulator. The inventions of these Groups have different functions, different effects, and different modes of operation.

The methods of Groups IV and VIII are patentably distinct. The invention of Group IV is drawn to a computational method for designing an androgen receptor synthetic ligand. The invention of Groups VIII is drawn to a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an AR modulator. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Group V and Group VI are related as method of identifying and product. In the instant case the AR modulator of Group VI practices in distinct inventions of Groups VII and VIII, drawn to a method for treating prostate cancer and a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an AR modulator, respectively. In addition, the AR modulator of Group VI can be practice in a method of molecular modeling using x-ray crystallography software, which is also a clearly distinct usage of the AR modulator.

The methods of Groups V and VII are patentably distinct. The invention of Group V is drawn to a method for identifying a compound that modulates androgen receptor activity, whereas the invention of Groups VII is drawn to a method for treating prostate cancer by administering an effective amount of an AR modulator. The inventions of these Groups have different functions, different effects, and different modes of operation.

The methods of Groups V and VIII are patentably distinct. The invention of Group V is drawn to a method for identifying a compound that modulates androgen receptor activity. The

invention of Groups VIII is drawn to a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an AR modulator. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Group VI and Group VII are related as product and process of use. In the instant case the AR modulator of Group VI practices in distinct inventions of Groups VII and VIII, drawn to a method for treating prostate cancer and a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an AR modulator, respectively. In addition, the AR modulator of Group VI can be practiced in a method of molecular modeling using x-ray crystallography software, which is also a clearly distinct usage of the AR modulator.

The inventions of Group VI and Group VII are related as product and process of use. In the instant case the AR modulator of Group VI is used in alternative inventions of Groups VII and VIII, drawn to a method for treating prostate cancer and a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an AR modulator, respectively. In addition, the AR modulator of Group VI can be practiced in a method of molecular modeling using x-ray crystallography software, which is also a clearly distinct usage of the AR modulator.

The inventions of Group VI and Group VIII are related as product and process of use. In the instant case the AR modulator of Group VI is used in distinct inventions of Groups VII and VIII, drawn to a method for treating prostate cancer and a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an

AR modulator, respectively. In addition, the AR modulator of Group VI can be practice in one of the steps of the invention Group V such as molecular modeling, which is also a clearly distinct usage of the AR modulator.

The inventions of Groups VII and VIII are patentably distinct. The invention of Group VII for treating prostate cancer is not required for a method for treating age related disease (as an osteoporosis, muscle wasting or loss of libido) by administering an effective amount of an AR modulator of Group VIII.

All Groups would require a distinct and different search with minimal overlap thus documenting the undue search burden of searching.

SPECIE ELECTION REQUIREMENT FOR GROUP I:

This application contains claim directed to the following patentably distinct species of the claimed invention: These species are distinct because they each add a feature to a crystal of an AR-LBD AND for binding site or ligands with different structures and distinct functions which each would require a separate and burdensome search to add to the search for the basic detection molecule as defined above.

Group I:

Specie IA: no ligand;

Specie IB: with ligand;

if this specie A or B is elected, then an election one of next specie is also required.

Specie IAA: whole enzyme AR-LBD;

Specie IBB: binding site only;

Specie ICC: part of ligand binding site.

Applicants are advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, the specie elections for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR § 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai Galitsky, Ph.D., whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 8:30 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 26, 2002

NMG

ARDIN H. MARSCHEL
PRIMARY EXAMINER